REMARKS

Reconsideration of the patentability of applicants' claims is requested respectfully.

Status of the Claims

The Examiner's Action addresses all of applicants' elected claims, namely Claims 1, 3, 6, 7 and 27 to 38. Claim 1 has been amended. Claims 27, 29, 31 and 34 have been cancelled. Accordingly, there is presented for the Examiner's consideration Claims 1, 3, 6, 7, 28, 30, 32, 33, and 35 to 38.

Summary of the Examiner's Rejections

In response to applicants' Reply dated November 10, 2003, the Examiner has not reasserted the rejections in her Action of July 8, 2003, but has asserted new rejections.

Claims 1, 6, 7, 27 to 31, 34, 35, 37 and 38 have been rejected under 35 U.S.C. §103 (a) as being obvious in view of the disclosure of U.S. Patent No. 5,603,947 to Wong et al. (hereafter "the Wong et al. reference") in view of the disclosure of U.S. Patent No. 5,914,282 to Dunshee et al. (hereafter, "the Dunshee et al. reference").

Claims 3, 32, 33, and 36 have been rejected under 35 U.S.C. § 103 (a) as being obvious in view of the disclosure of the Wong et al. reference in view of the disclosures of the Dunshee reference and U.S. Patent No. 5,316,759 to Rose et al. (hereafter "the Rose et al. reference").

Reconsideration of the Examiner's rejections is requested respectfully.

Summary of Applicants' Invention

Applicants' invention is summarized in the Reply that was filed on March 15, 2002. As reflected in applicants' Claims 1 and 27 and as described in detail in the March 15 Reply, two features which distinguish applicants' transdermal patch over the prior art are: (i) a solid silicone adhesive layer which contains a normally volatile drug (for example, nicotine) and which is a source in the patch of the drug; and (ii) a solid acrylic adhesive layer which underlies (viewed from the area of skin contact) the silicone adhesive layer and which is in diffusional contact therewith. The resins comprising these layers and the positioning of the layers in the patch are critical to the effective manufacture of the patch and to its successful functioning.

As to the drug-containing layer, volatile drug in the patch is contained initially in the layer of silicone adhesive which is highly soluble in a high vapor pressure solvent, for example, hexane. In forming applicants' patch, a layer containing the volatile drug is formed from a solution of the volatile drug, the silicone adhesive, and the high vapor-pressure solvent by casting a film of the solution and evaporating the solvent. The solvent evaporates readily at a relatively low temperature, that is, at a temperature at which loss of the volatile drug is minimized or avoided during the drying process which leads to formation of the solid layer of the drug-containing silicone adhesive. In contrast, the use of an adhesive (as the drug-containing adhesive) which is not highly soluble in a high vapor-pressure solvent and which requires the use of a solvent that has a relatively low vapor pressure (thus, requiring the use of relatively high "evaporating" temperatures) would result in the loss of a substantial amount of the volatile drug during the manufacturing process.

As to the acrylic adhesive layer which underlies the drug-containing silicon adhesive layer, the rate of drug diffusion through the acrylic adhesive is slower than the diffusion rate through a silicone adhesive. Accordingly, there is a controlled diffusion of the drug from the acrylic adhesive layer to the skin over a sustained period of time.

Summary of the Disclosures of the References

The disclosure of each of the references is summarized below.

U.S. Patent No. 5,603,947 to Wong *et al.*

The Wong et al. reference discloses a patch which releases the bulk of its nicotine loading over a very short period of time (see Col. 5, lines 25 to 35); it teaches away from a patch which functions to release nicotine over a sustained period as claimed by applicants. The Wong et al. patch comprises: (A) an impermeable backing layer; (B) a silicone adhesive layer containing nicotine; and (C) a release liner. The Wong et al. reference does not disclose a patch which includes an acrylic adhesive layer, which is an element of applicants' claimed patch.

U.S. Patent No. 5,914,282 to Dunshee *et al.*

The Dunshee reference describes an adhesive composite sheet for use with a wound dressing or for use as an adhesive tape for skin contact. The composite sheet comprises a porous backing layer which has laminated thereto a polymeric barrier layer which, in turn, has adhered thereto to a skin-contacting adhesive layer. Prior to application to the skin, the skin-contacting adhesive layer has adhered thereto a release liner. Optionally, for use in a wound dressing, an adsorbent pad may reside between a portion of the adhesive layer and the release liner. The Dunshee reference describes broadly, for skin contact, acrylic-based adhesives which can include polymers prepared by copolymerizing one or more ethylene moiety-containing compounds with one or more of an acrylic acid compound and an acrylic acid ester compound, including isooctylacrylate and ethyl(hexyl)acrylate compounds.

There is no disclosure whatsoever in the Dunshee reference respecting the use of a silicone-based adhesive or of the use of a drug. Indeed, the Dunshee reference does not disclose a transdermal patch or any device having an adhesive layer through which a drug diffuses.

U.S. Patent No. 5,316,759 to Rose et al.

The Rose et al. reference discloses a transdermal patch in which the drug source is a liquid solution containing a drug or a neat liquid drug. In the Rose et al. patch, the drug source is contained in a pouch formed by a liquid-impermeable backing layer and a liquid-permeable, skin-contacting layer which can comprise, for example, "...cotton material or a similar cloth-like material..." (Col. 8, lines 43-61). The Rose et al. reference discloses further that, in the case in which the drug source for the patch is a liquid drug solution, the solution can be contained in "micro-sealed compartments" (Col. 8, line 67 - Col. 9, line 2), as described in the Sanvordeker et al. patent (cited by Rose et al.). The Sanvordeker patent describes the compartments as a matrix of "silicone rubber having from about 10 to 200 micron micro-sealed compartments being formed by in situ cross-linking of the silicone rubber after it is mixed with the hydrophilic solvent system containing ...[a drug]... and the hydrophobic solvent system" (Sanvordeker et al. Col. 3, lines 32-38).

The Rose et al. reference discloses further that "The exact details of the patch are not critical to the present invention..." and cites U.S. Patent Nos. 3,731,683 and 3,797,494 both to Zaffaroni and 4,336,243 to Sanvordeker et al. as illustrative of the patches which can be utilized in the Rose et al. development. None of these patents discloses the transdermal patch of applicants' development.

Discussion and Traversal of the Examiner's § 103 Rejections

It is submitted respectfully that the Examiner's rejections are not sound and, accordingly, should be withdrawn because, among other reasons, the Examiner has failed to establish a *prima facie* case of obviousness. The law is clear. To establish a *prima facie* case of obviousness, it must be shown that: (A) there is some suggestion or motivation, either in the cited documents themselves or in the knowledge of those skilled in the art, to modify or combine the cited disclosures; (B) there must be a reasonable expectation that the modification or combination of the cited disclosures would lead to a successful result; and (C) the combined disclosures must teach or suggest all of the elements of the claim. MPEP § 2143. All three of these requirements must be satisfied for the Examiner to establish a *prima*

*facie* case of obviousness. If any one such requirement is not satisfied, then the Examiner must withdraw the rejection.

The following discussion shows that at least two of the aforementioned requirements have not been satisfied. Accordingly, the Section 103 rejections should be withdrawn and the Examiner's request for data showing criticality is misplaced (see "Interview Summary", dated May 6, 2004).

Discussion of the Examiner's §103 Rejection Based on the
Disclosure of the Wong et al. reference in view of the Dunshee et al. reference.

This rejection is traversed respectfully.

As pointed out above, the primary reference (Wong et al.) discloses a patch which releases the bulk of the nicotine contained therein in a very short period of time; accordingly, the primary reference discloses a patch which is just the opposite of applicants' claimed patch which functions to release nicotine over a prolonged period of time, for example, several hours as set forth in amended Claim 1 or for up to 72 hours, as set forth in Claim 36. Applicants' generic Claim 1 distinguishes over the disclosure of Wong et al. in various ways, including defining a patch which has a solid acrylic adhesive layer (not an element of the Wong et al. patch) and in reciting in explicit terms sustained release of the drug contained in the patch.

The secondary reference (the Dunshee et al. patent) does not even disclose a transdermal patch, as discussed above.

It is abundantly clear that the combined disclosures of the references contain no suggestion that would lead one skilled in the art to modify the "immediate" release patch of the primary reference in a manner, as proposed by the Examiner, to convert it to a "sustained" release patch as set forth in applicants' claims. If the Examiner persists in her rejection, it is requested that she explain what disclosures exists in either the primary or secondary reference that would lead one skilled in the art to make the modification while at the same time

preserving the "immediate" release properties of the Wong et al. patch which is what the Wong et al. reference is all about.

Furthermore, the Examiner's rejection is deficient in that there is absolutely no disclosure in either the primary or secondary reference that would enable one to conclude that applicants' patch would reasonably be expected to function as a successful "sustained" release patch, as set forth in applicants' claims.

In view of the above, it is abundantly clear that the Examiner has failed to establish a *prima facie* case of obviousness, as the law demands, in that at least two of the three requirements that are necessary to establish a *prima facie* case of obviousness have not been met.

It is submitted respectfully that the Examiner in issuing her rejection has ignored basic principles of law that are associated with a determination of obviousness and has based her rejection inappropriately on subjective criteria utilizing the benefits of applicants' disclosure, that is, criteria based on the impermissible use of hindsight.

In view of the above, it is requested respectfully that the Examiner withdraw her § 103 (a) rejection.

Discussion of the Examiner's §103 Rejection Based
on the Disclosure of Wong et al. Reference in View
of the Disclosures of Dunshee et al. Reference and the Rose Reference

This rejection, which includes the additional citation of the Rose reference, is traversed also.

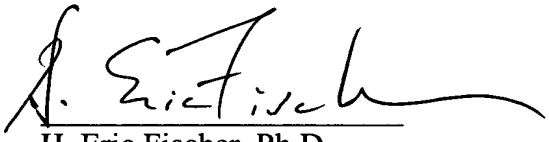
Applicants acknowledge, as stated by the Examiner, that the Wong et al. and Dunshee et al. references do not disclose a patch which includes a mixture of nicotine and mecamylamine as set forth in Claims 3, 32 and 33, or the 72 hour period of drug administration as set forth in Claim 36.

Applicants submit respectfully that the additional citation of the Rose reference does not in any way cure the deficiencies of the Wong et al. and Dunshee et al. references as discussed above in connection with the Examiner's rejection based on their disclosures. Accordingly, it is requested respectfully that the Examiner withdraw the §103 rejection based on the disclosures of the three aforementioned references.

In view of the above, it is requested respectfully that the Examiner allow the application in an early and favorable action.

This Reply is accompanied by a Petition for Extension of Time to respond to the Examiner's Action.

Respectfully submitted,



H. Eric Fischer, Ph.D.
Registration No. 46,010

Synnestvedt & Lechner LLP
2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107
Telephone (215) 923-4466
Facsimile (215) 923-2189
efischer@synnlech.com